

## Exhibit 300: Capital Asset Plan and Business Case Summary

### Part I: Summary Information And Justification (All Capital Assets)

#### Section A: Overview (All Capital Assets)

**1. Date of Submission:** 2010-03-17 14:11:15

**2. Agency:** 009

**3. Bureau:** 10

**4. Name of this Investment:** FDA Mission Accomplishments and Regulatory Compliance Services

**5. Unique Project (Investment) Identifier:** 009-10-01-03-01-8021-00

**6. What kind of investment will this be in FY 2011?:** Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

**7. What was the first budget year this investment was submitted to OMB? \***

**8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.**

The MARCS program manages the integration, reengineering and enhancement of seven legacy systems to better support FDA's mission. It aligns directly with Objective 2.2 of the HHS strategic plan: Protect the Public Against Injuries and Environmental Threats, enables FDA Centers to meet FDA Strategic Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain, and helps support PMA Expanded E-Government. FDA uses MARCS' applications to: plan FDA field activities and assign staff to inspections, investigations, recalls and other compliance activities; track and control samples and the results of laboratory analysis; collect and maintain information from field activities; collect performance data, particularly that related to FDAAA; send Prior Notice for food imports to Customs and accept import product information from Customs for screening; screen 20 million import lines a year based on calculated risk; collect information about the facilities FDA regulates and those in the import supply chain for risk-based targeting; provide FDA Centers with information on inspections, compliance actions, recalls, laboratory analysis and facilities. MARCS fills the current performance gap by providing for 1 the convergence of Center and ORA workflows, in particular for compliance, recalls, and complaints 2 the convergence of Imports and Domestic workflows by reengineering and integrating components 3 better cooperation through electronic communication with industry, academia, and state and local organizations through such components as eSAF, ITACS, and CLEARs 4 a national workforce where resources can be assigned using WAAM and ARRMS to any area of the USA rather than being confined to only one geographical area. 5 reusable services for MARCS and other FDA investments to reduce duplication of effort This is being accomplished by phasing out legacy functionality bit by bit. The completed migrations to the Web and UNIX, the services for SERS and NSD, and PREDICT are examples of the integration, reengineering, and enhancement that have replaced or improved upon legacy functionality. MARCS will integrate with Harmonized Inventory for FDA-wide Product Quality, giving FDA a common, authoritative data source for firm and product data. Additional integration with other FDA investments such as ALM, RBIS, and cEDR will enhance functionality. MARCS will also support functionality for tobacco regulation.

- a. Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned) alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

**9. Did the Agency's Executive/Investment Committee approve this request? \***

a. If "yes," what was the date of this approval? \*

**10. Contact information of Program/Project Manager?**

- Name: \*
- Phone Number: \*
- Email: \*

**11. What project management qualifications does the Project Manager have? (per FAC-P/PM)? \***

- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

**12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):**

Financial management system name(s)	System acronym	Unique Project Identifier (UPI) number
*	*	*

**a. If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one): \***

- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

## Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

<b>Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES</b> <b>(REPORTED IN MILLIONS)</b> (Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)									
	PY1 and earlier	PY 2009	CY 2010	BY 2011	BY+1 2012	BY+2 2013	BY+3 2014	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition:	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
SUBTOTAL:	*	*	*	*	*	*	*	*	*
Government FTE Costs should not be included in the amounts provided above.									
Government FTE Costs	*	*	*	*	*	*	*	*	*
Number of FTE represented by Costs:	*	*	*	*	*	*	*	*	*
TOTAL(including FTE costs)	*	*	*	*	*	*	*	*	*

2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:

\*

## Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table 1: Contracts/Task Orders Table

Contract or Task Order Number	Type of Contract/Task Order (In accordance with FAR Part 16)	Has the contract been awarded (Y/N)	If so what is the date of the award? If not, what is the planned award date?	Start date of Contract/Task Order	End date of Contract/Task Order	Total Value of Contract/Task Order (M)	Is this an Interagency Acquisition? (Y/N)	Is it performance based? (Y/N)	Competitively awarded? (Y/N)	What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A)	Is EVM in the contract? (Y/N)
Various--Contracts completed in prior years	CPFF: Cost Plus Fixed Fee	Y	2003-09-30	2003-09-30	2005-09-30	\$7.7	*	*	*	*	*
HHSF223200550072W	CPFF: Cost Plus Fixed Fee	Y	2005-04-08	2005-04-08	2007-09-30	\$6.5	*	*	*	*	*
HHSF223200550067W	CPFF: Cost Plus Fixed Fee	Y	2005-04-01	2005-04-01	2007-09-30	\$8.6	*	*	*	*	*
HHSF223200550262G	T&M: Time & Materials	Y	2005-07-01	2005-07-01	2010-06-30	\$5.2	*	*	*	*	*
HHSF22320055003C	CPFF: Cost Plus Fixed Fee	Y	2005-09-01	2005-09-03	2008-08-31	\$2.0	*	*	*	*	*
IAG 224-07-4004	LH: Labor Hour	Y	2005-01-27	2005-01-28	2010-06-30	\$4.9	*	*	*	*	*
HHSF223200550297G	T&M: Time & Materials	Y	2005-01-12	2005-01-12	2008-05-09	\$8.6	*	*	*	*	*
HHSF223200650508	CPFF: Cost Plus Fixed Fee	Y	2006-09-22	2006-10-02	2008-08-31	\$1.3	*	*	*	*	*
HHSF223200750357W	CPFF: Cost Plus Fixed Fee	Y	2007-08-26	2007-09-01	2010-06-30	\$20.6	*	*	*	*	*
DAAE30-99-D-1013	FFP: Firm Fixed Price	Y	2009-03-01	2009-03-01	2010-03-31	\$1.9	*	*	*	*	*
HHSF223200950003C	T&M: Time & Materials	Y	2009-05-26	2009-05-26	2010-05-25	\$3.5	*	*	*	*	*
INN10PC18073	FFP: Firm Fixed Price	Y	2009-11-24	2009-12-31	2014-11-23	\$98.0	*	*	*	*	*

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

\*

3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements? \*

a. If "yes," what is the date? \*

## Section D: Performance Information (All Capital Assets)

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2006	Effective Management of Human Capital/Information Technology/Resources	*	*	% of infrastructure brought to current standard (web from c/s). outcome: improved application maintainability and reduced cost	0% of infrastructure	100% of infrastructure	success. 100% of existing legacy converted from c/s to web
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of import product types screened based on calculated risk factors. outcome: higher may proceed rate for low risk products, more resources for higher risk food products	0 food product types	development of pilot for screening	success. completed
2006	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% reduction in complaints about printing capabilities in the field. outcome: increased customer satisfaction and productivity for field employees	ongoing complaints	100% reduction	success. 100% --release of enhancements packaged with web version of facts/oasis eliminated all print complaints
2006	Effective Management of Human Capital/Information Technology/Resources	*	*	# of districts that have automated support for assignment & scheduling. outcome: improved management of worker resources	0 districts	19 districts	success. 19 districts. completed
2007	Effective Management of Human Capital/Information Technology/Resources	*	*	# of center registration systems accessed via center views. outcome: greater efficiency of import reviewers due to faster information sharing	0 systems	4 systems	success. 4 center systems accessed via web through center views
2007	S.O. 2.2 - Protect the public against injuries and environmental	*	*	# of import product types screened based on calculated risk factors.	0 food product types	1 food product type	success. 1 product type (seafood) tested

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	threats			outcome: higher may proceed rate for low risk products, more resources for higher risk food products			
2007	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	14,000,000 imported products	15,000,000 imported products	success. 15,000,000 imported products
2007	Effective Management of Human Capital/Information Technology/Resources	*	*	% of interfaces with center databases standardized. outcome: greater workflow efficiency and more effective decision making resulting in stronger enforcement cases	20% of interfaces	70% of interfaces	failure. goal not met. work delayed.
2007	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of states that have access to an automated checklist for bse threat analysis. outcome: enables the states to conduct effective bse inspections	0 states	50 states	success. 50 states
2008	Effective Management of Human Capital/Information Technology/Resources	*	*	% of infrastructure brought to current standard (vms to unix). outcome: reliable infrastructure supporting key agency missions	20% of infrastructure	80% of infrastructure	success. unix i implemented. all major systems and databases (80% of infrastructure) now at current standard.
2008	Effective Management of Human Capital/Information Technology/Resources	*	*	# of center registration systems accessed via	4 systems	6 systems	success. center views accesses 8 center systems.

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				center views. outcome: greater efficiency of import reviewers due to faster information sharing			
2008	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: greater efficiency for investigators, analysts, and compliance officers	0% of functionality	20% of functionality	success. single sign on and firm finder (20% of functionality).
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of import product types screened based on calculated risk factors. outcome: higher may proceed rate for low risk products, more resources for higher risk food products	1 food product type	3 food product types	failure. predict pilot supports 1 food product type.
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	15,000,000 imported products	16,000,000 imported products	success. more than 16,000,000 imported products.
2008	Effective Management of Human Capital/Information Technology/Resources	*	*	% comments are complaints about screens. outcome: increased user satisfaction and productivity.	65% of comments are complaints	60% of comments are complaints	success. complaints reduced to less than 60%.
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of sources automatically mined for bioterrorism food processing. outcome: lower	0 sources	1 source	success. predict pilot automatically mines 1 source.

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				risk of imminent threats due to food			
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of compliance actions share automated workflow actions and evidence captured with centers. outcome: increased efficiency and speed in producing successful performance cases	0% of compliance actions	20% of compliance actions	success. data pulled from domestics into case management system (20% of compliance actions).
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: decreased cost of assigning staff to inspections	20% of workforce functions	25% of workforce functions	success. national sample distributor implemented (25% of workforce functions).
2008	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of work functions available on mobile devices. outcome: decreased amount of time needed to perform inspections, investigations, exams, and collections	2 work functions	3 work functions	success. establishment inspection report, 483 (adverse observations), and international mail facility
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of infrastructure brought to current standard (vms to unix). outcome: reliable infrastructure supporting key agency missions	80% of infrastructure	100% of infrastructure	success. 100% of infrastructure
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	% of interfaces with center databases standardized. outcome: greater information access and more effective decision making resulting in	0% of interfaces	20% of interfaces	success. 20% of interfaces



Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				stronger enforcement cases			
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and compliance functions	20% of functionality	36% of functionality	success. 36% of functionality
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of import product types screened based on calculated risk factors. outcome: higher may proceed rate for low risk products, more resources for higher risk food products	1 food product type	80% of food product types	success. 100% of food product types
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported product lines screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	16,000,000 imported product lines	17,000,000 imported product lines	success. 17,000,000 imported products
2009	Effective Management of Human Capital/Information Technology/Resources	*	*	% comments are complaints about screens. outcome: increased user satisfaction and productivity.	60% of comments are complaints	55% of comments are complaints	success. 54% of comments are complaints
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of sources automatically mined for risk based bioterrorism food processing. outcome: lower risk of imminent threats due to food	1 source	2 sources	success. 2 sources

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of compliance actions share automated workflow actions and evidence captured with centers. outcome:	20% of compliance actions	30% of compliance actions	success. 30% of compliance actions
2009	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource management for assigning and managing nationwide inspection staff	25% of workforce functions	30% of workforce functions	success. 30% of workforce functions
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% of infrastructure 24/7 compliant that is required to be 24/7 compliant. outcome: compliance with bioterrorism act to check every food product and conformation to customs and border patrol's two hour time window	0% of infrastructure	100% of infrastructure	tbd
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% of interfaces with center databases standardized. outcome: greater information access and more effective decision making resulting in stronger enforcement cases	20% of interfaces	70% of interfaces	tbd
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and	36% of functionality	48% of functionality	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				compliance functions			
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of import product types screened based on calculated risk factors. outcome: higher may proceed rate for low risk products, more resources for higher risk drug products	0% of drug product types	80% of drug product types	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported product lines screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	17,000,000 imported product lines	18,000,000 imported product lines	tbd
2010	Effective Management of Human Capital/Information Technology/Resources	*	*	% of comments is complaints about screens. outcome: increased user satisfaction and productivity.	55% of comments are complaints	50% of comments are complaints	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of sources automatically mined for risk based bioterrorism food processing. outcome: lower risk of imminent threats due to food	2 sources	3 sources	tbd
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of compliance actions share automated workflow actions and evidence captured with centers. outcome: ora can produce more successful performance cases	30% of compliance actions	40% of compliance actions	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2010	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of compliance actions share automated workflow actions and evidence captured with centers. outcome: improved resource management for assigning and managing nationwide inspection staff	30% of workforce functions	45% of workforce functions	tbd
2011	Effective Management of Human Capital/Information Technology/Resources	*	*	% of interfaces with center databases standardized. outcome: greater information access and more effective decision making resulting in stronger enforcement cases	70% of interfaces	80% of interfaces	tbd
2011	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and compliance functions	48% of functionality	60% of functionality	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of import product types screened based on calculated risk factors. outcome: higher may proceed rate for low risk products, more resources for higher risk device products	0% of device product types	80% of device product types	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported product lines screened per year within a window of two hours. outcome: meeting the two hour time window available for	18,000,000 imported product lines	19,000,000 imported product lines	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)			
2011	Effective Management of Human Capital/Information Technology/Resources	*	*	% of comments are complaints about screens. outcome: increased user satisfaction and productivity.	50% of comments are complaints	45% of comments are complaints	tbd
2011	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource management for assigning and managing nationwide inspection staff	45% of workforce functions	60% of workforce functions	tbd
2012	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and compliance functions	60% of functionality	68% of functionality	tbd
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	19,000,000 imported products	20,000,000 imported products	tbd
2012	S.O. 2.2 - Protect the public against	*	*	% of comments is complaints about screens.	45% of comments are complaints	40% of comments are complaints	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	injuries and environmental threats			outcome: increased user satisfaction and productivity.			
2012	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource management for assigning and managing nationwide inspection staff	60% of workforce functions	70% of workforce functions	tbd
2013	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and compliance functions	68% of functionality	76% of functionality	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	20,000,000 imported products	21,000,000 imported products	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of comments is complaints about screens. outcome: increased user satisfaction and productivity.	40% of comments are complaints	35% of comments are complaints	tbd
2013	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource	70% of workforce functions	80% of workforce functions	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				management for assigning and managing nationwide inspection staff			
2014	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for certain investigation, analysis, and compliance functions	76% of functionality	84% of functionality	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	21,000,000 imported products	22,000,000 imported products	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of comments is complaints about screens. outcome: increased user satisfaction and productivity.	35% of comments are complaints	30% of comments are complaints	tbd
2014	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource management for assigning and managing nationwide inspection staff	80% of workforce functions	90% of workforce functions	tbd
2015	Effective Management of Human Capital/Information Technology/Resources	*	*	% disparate functionality harmonized between legacy systems. outcome: reduction in time required for	84% of functionality	92% of functionality	tbd

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
				certain investigation, analysis, and compliance functions			
2015	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	# of imported products screened per year within a window of two hours. outcome: meeting the two hour time window available for screening from customs and border patrol operations as required by law. reduced impact on commerce (cost to industry)	22,000,000 imported products	23,000,000 imported products	tbd
2015	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of comments is complaints about screens. outcome: increased user satisfaction and productivity.	30% of comments are complaints	25% of comments are complaints	tbd
2015	S.O. 2.2 - Protect the public against injuries and environmental threats	*	*	% of workforce planning/scheduling functions in current stovepipes integrated. outcome: improved resource management for assigning and managing nationwide inspection staff	90% of workforce functions	100% of workforce functions	tbd



## Part II: Planning, Acquisition And Performance Information

### Section A: Cost and Schedule Performance (All Capital Assets)

#### 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
COMPLETED MARCS OPERATION S DME: Baseline Systems Web Migration, Tactical Work Plan Pilot, Design/Devel opment, Stand up test and operational environment to support 24/7; MARCS External Interface, User Access; MARCS Interface, Integration with portal	\$16.3	\$16.3	2005-08-30	2005-08-30	2008-09-30	2008-09-30	100.00%	100.00%
COMPLETED MARCS SERVICES DME: Standardized Evidence Reference Services Planning & Acquisition; Standardized Evidence Reference Services Prototype; National Sample Distributor	\$1.8	\$1.8	2005-06-30	2005-06-30	2008-03-21	2008-03-21	100.00%	100.00%
COMPLETED MARCS MANAGEMENT DME: Preliminary Planning, Requirements , Design, Feasibility, Database Redesign/Res tructure; FY06 Management Reserve; Security (through FY08); EA, Quality	\$13.2	\$13.2	2004-06-01	2004-06-01	2008-09-30	2008-09-30	100.00%	100.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Assurance, CPIC (through FY08), Program Management (through FY08)								
Import Operations 1: ITACS, Enhanced Entry Review, PREDICT Integration, PN Targeting, PNSI Final Rule, PNSI Enhance Usability, PNSI Log in and Startup, PNSI Batch Submissions, enhance to browse status messages, error messages, CBP files, SQL menu	\$3.6	\$2.9	2008-10-01	2008-10-01	2010-09-30		84.96%	81.76%
Import Operations 2: Move all of OASIS off of Oracle forms. Move PNSI off of Oracle Forms, additional enhancements	*	*	2010-10-01		2012-09-30		0.00%	0.00%
PREDICT: Move from Pilot into Production. FY08 Supplemental Funds	\$1.9	\$1.6	2009-09-01	2009-09-01	2010-09-30		84.62%	84.89%
Domestic Operations 1: Seafood HACCP, retire compliance activity functionality once ALS is integrated, move parts of FACTS off of Oracle Forms, additional enhancements	\$1.6	\$1.1	2008-10-01	2008-10-01	2010-09-30		75.85%	71.70%
Domestic Operations 2:	*	*	2010-10-01		2012-09-30		0.00%	0.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Move all of FACTS off of Oracle forms, FACTS support for WAAM CAR, additional								
MARCS Operations 1: Requirements, Future enhancements	*	*	2012-10-01		2014-09-30		0.00%	0.00%
Recalls Enterprise System (RES) 1: Support for Centers, CBER Direct Recall Classification, MARCS Frame, separate email notifications as a start for Notification Services, medium and low center priorities	\$2.1	\$2.1	2005-06-30	2005-06-30	2009-06-30	2009-06-12	100.00%	100.00%
Recalls Enterprise System (RES) 2: Integration with SERS, Firm Finder, and PREDICT. Improved audit checking, mandatory spell check, enforcement report, product code conversion, application streamlining, reporting support, medium and low priorities	\$2.1	\$0.4	2009-07-01	2009-08-03	2011-06-30		19.36%	18.43%
Recalls Enterprise System (RES) 3: Requirements, future enhancement	*	*	2011-07-01		2013-06-30		0.00%	0.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
s (possibly Pre-Market, additional Center needs, international recalls)								
Field Work Manager (FWM) 1: Core, IMC, Field Exams	\$1.5	\$1.4	2008-04-01	2008-04-01	2009-09-30	2009-09-30	100.00%	100.00%
Field Work Manager (FWM) 2: Field Exams, Sample Collection, Recalls, Complaints, Investigations, Inspections, Compliance	\$2.4	\$0.9	2009-10-01	2009-10-01	2011-09-30		39.76%	38.94%
Field Work Manager (FWM) 3: Recalls, Complaints, Investigations, Inspections, Compliance	*	*	2011-10-01		2013-09-30		0.00%	0.00%
Center Views 2: Single Sign On, enhanced search capability, display for information from CDER and CFSAN systems, CBER and CDRH tab enhancements	\$0.4	\$0.3	2009-08-01	2009-09-21	2010-09-30		96.40%	83.22%
Compliance Management System	\$1.0	\$0.1	2009-10-01	2009-12-31	2011-09-30		8.48%	8.04%
Contract Laboratory Evaluation and Review System (CLEARS): Requirements, Contract Laboratory Accreditation Registry and Tracking, Advance Notice Intent to use Accredited Laboratory,	\$3.0	\$0.3	2009-08-01	2009-12-31	2011-09-30		11.21%	10.16%

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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Submission and Review of Abbreviated and Full Laboratory Packages								
Activity Log Service (ALS) 1: Triggers in Domestic to ALS, modify Domestics to view activities	\$1.7	\$1.6	2006-06-01	2006-06-01	2009-08-31	2009-08-31	100.00%	100.00%
Activity Log Service (ALS) 2: UI for searching, creating, modifying, and annotating activities	*	*	2009-10-01		2010-06-30		100.00%	0.00%
Activity Log Service (ALS) 3: Reporting support, administration module UI	*	*	2010-07-01		2011-03-31		4.00%	0.00%
Notification Services: Email notifications	\$0.5	\$0.4	2009-09-01	2009-12-31	2010-09-30		81.82%	80.38%
Work Assignment and Accomplishment Manager (WAAM) 1: Requirements, Tactical Work Planner, Work Assignment Manager, Time Reporter, Compliance Achievement Reporter (CAR), Accomplishment Reporting, National Work Distributor	\$3.5	\$0.3	2009-12-01	2009-12-31	2011-10-31		10.19%	9.89%
Work Assignment and Accomplishment Manager (WAAM) 2: Requirements, Tactical Work Planner, Compliance	*	*	2011-08-01		2013-07-31		0.00%	0.00%

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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Achievement Reporter (CAR),								
Data Sharing Service (DSS) 1: Support for PREDICT, support for Center Views, marketing status data, locator functionality. Includes 1,500 FY08 Supplemental Funds	\$2.0	\$0.1	2009-07-01	2009-08-01	2010-09-30		14.00%	5.19%
Data Sharing Service (DSS) 2: Requirements, Access to ORA databases	*	*	2010-07-01		2012-06-30		1.10%	0.00%
Standardized Evidence Reference Services (SERS) 2: Link electronic documents, user interface	\$0.2	\$0.3	2008-09-01	2008-09-01	2009-08-31	2009-08-31	100.00%	100.00%
Standardized Evidence Reference Services (SERS) 3: Requirements, complete user interface, metadata redesign, future enhancements	\$1.0	\$0.8	2009-09-01	2009-09-01	2011-09-30		80.63%	78.66%
Business Document Creator Service (BDCS): Requirements, set of document templates, code to access and produce documents for compliance, investigations, inspections, etc.	*	*	2010-06-01		2013-03-31		0.50%	0.00%

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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Data Look Up and Code Management Service (DLCMS): Requirements, capability for designated users to change, add, and delete codes (such as PAC codes) used in lookup tables and selections	*	*	2010-10-01		2012-09-30		0.00%	0.00%
User Workspace Management (UWM): Requirements, allows users to store filter, search, and display options for all applications	*	*	2011-10-01		2012-09-30		0.00%	0.00%
Integration Within MARCS 1: Feasibility of migrating character-based and other applications, investigate design alternatives, Imports IMF integration, SERS and Turbo integration. OASIS FACTS Field Exam Integration, Accomplishment Hours, User Roles	\$3.3	\$2.4	2008-10-01	2008-10-01	2010-09-30		74.28%	72.81%
Integration Within MARCS 2: Imports and Domestics integration with ALS to access administration module. Integration between services and Imports, Domestics, RES, FWM,	*	*	2010-10-01		2012-09-30		0.00%	0.00%

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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
WAAM. Integration between WAAM and Imports, Domestics, RES, FWM								
Integration Within MARCS 3: Continued integration with services and between components, SERS and DSS integration	*	*	2012-10-01		2014-09-30		0.00%	0.00%
Integration with Other FDA Investments 1: MARCS Firm Management Service Integration, FACTS and CMS Integration, SERS integration, Imports and Domestics integration with RBIS. Integration with FURLS (HI) (PNSI, eSAF, ITACS), ALM (QMIS), RBIS, PQC	\$1.5	\$1.3	2008-10-01	2008-10-01	2010-09-30		88.14%	86.59%
Integration with Other FDA Investments 2: Integration with ALM, RBIS, CMS, EON, HI for product information, PQC, FASTAR for services, cEDR	*	*	2010-10-01		2012-09-30		0.00%	0.00%
Integration with Other FDA Investments 3: Integration with ALM, RBIS, EON, HI for product information,	*	*	2012-10-01		2014-09-30		0.00%	0.00%



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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
PQC, FASTAR for services								
Integration Outside FDA 1: State Systems Automated Interface to eSAF, eSAF Non-contracted State Inspections, eSAF State Data Transfer, eSAF Support for Additional Programs, ITDS/ACE, USDA, DHS, CDC	\$0.6	\$0.5	2008-10-01	2008-10-01	2010-09-30		87.32%	87.44%
Integration Outside FDA 2: RES 2 integration with the States, VA, USDA, other Federal Agencies, other national governments. MARCS integration with the States, VA, USDA, DHS, CDC, other Federal Agencies, other national governments	*	*	2010-10-01		2012-09-30		0.00%	0.00%
Integration Outside FDA 3: MARCS integration with the States, VA, USDA, DHS, CDC, other Federal Agencies, other national governments	*	*	2012-10-01		2014-09-30		0.00%	0.00%
Management Reserve: Funds in reserve to deal with Congressional mandates or emergencies that can not be determined in advance such as a	*	*	2009-10-01		2013-09-30		0.98%	0.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
greater focus on imports, domestics, recalls, compliance and prosecution, international cooperation, etc.								
Security: Authorization, Roles, and Responsibilities Management Service, FDA FTEs, contractors, POA&M, C&A.	\$7.1	\$0.9	2008-10-01	2008-10-01	2013-09-30		14.73%	12.47%
EA CPIC: FDA FTEs, contractors, CPIC, E-300, EA.	\$3.4	\$0.6	2008-10-01	2008-10-01	2013-09-30		22.46%	18.83%
Program Management: FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, and planning.	\$9.9	\$3.8	2008-10-01	2008-10-01	2013-09-30		41.66%	38.90%
Long term Enhancements to address Regulatory Changes and FDA Environment Change	*	*	2013-10-01		2019-09-30		0.00%	0.00%
COMPLETED MARCS SS: SS Operations FY06-, SS Operations FY07, SS Operations FY08	\$10.4	\$10.4	2005-10-01	2005-10-01	2008-09-30	2008-09-30	100.00%	100.00%
VMS to Unix Migration Phase 1 (Production DB)	\$1.2	\$1.2	2006-03-31	2006-03-31	2008-08-15	2008-08-15	100.00%	100.00%
SS Operations FY09	\$3.9	\$3.7	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
VMS to Unix	\$0.8	\$0.8	2008-01-10	2008-01-10	2009-06-30	2009-06-19	100.00%	100.00%

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Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Migration Phase 2 (Back End DB)								
SS PREDICT FY09: Expansion of Risk Rules, Training. FY08 Supplemental Funds	\$0.7	\$0.7	2008-10-01	2008-10-01	2009-09-30	2009-10-09	100.00%	100.00%
SS Operations FY10	\$8.0	\$5.0	2009-10-01	2009-10-01	2010-09-30		79.03%	73.65%
SS Operations FY11	*	*	2010-10-01		2011-09-30		0.00%	0.00%
SS Operations FY12	*	*	2011-10-01		2012-09-30		0.00%	0.00%
SS Operations FY13	*	*	2012-10-01		2013-09-30		0.00%	0.00%
SS Operations FY14 - FY19	*	*	2013-10-01		2019-09-30		0.00%	0.00%

\* - Indicates data is redacted.